



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/752,032	11/19/96	BOYCE	F 00786/20600

JANIS K FRASER
FISH AND RICHARDSON
225 FRANKLIN STREET
BOSTON MA 02110-2804

18N2/1222

EXAMINER

CAMPELL, B

ART UNIT PAPER NUMBER

1819

9

DATE MAILED:

12/22/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 10/8/97
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☐ Claim(s) 1-21-26 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 1 is/are allowed.
- ☒ Claim(s) 21-26 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirements.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice Re Sequence Rules

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

The amendment and declaration of Frederick M. Boyce filed October 8, 1997 have been entered.

The specification does not comply with the rules for nucleotide sequence disclosures, 37 CFR 1.821-1.825. The specification contains nucleotide sequences that are not identified by SEQ ID No. at p. 7, lines 19-20. Sequences must be identified by SEQ ID No. each time they are mentioned in the disclosure. See 37 CFR 1.821(d). Correction may require submission of a new sequence listing. If so, Applicants must submit a substitute sequence listing in both computer readable and paper forms, a statement that the two forms are identical, and an amendment directing the entry of the paper form into the specification. The specification should also be amended to identify the sequences pointed out above by SEQ ID No. See the attached "Notice to Comply."

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 26 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 26 of copending Application No. 08/311,157. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The provisional obviousness-type double patenting rejection of claim 1 is withdrawn in view of the amendment to the claim. Since *in vitro* methods were elected in both 08/311,157 and allowed application 08/486,341, the *in vivo* method claimed in the instant application is distinct.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1819

Claims 21-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as previously stated (paper 4, pp. 3-6).

Applicant argues that the specification is enabling, citing the Boyce declaration. This argument is not persuasive. While the declaration demonstrates that baculovirus can be used to transiently express exogenous genes in a variety of cell types by *in vivo* administration, it does not show that one skilled in the art would be able to obtain a significant therapeutic benefit from such expression without undue experimentation. As stated in the previous Office action, sustained, high-level expression of introduced genes (required for gene therapy) is not routinely obtainable by those skilled in the art. Applicant's own publication (Boyce et al., ref. ES) shows that gene expression "peaks 12-24 hr postinfection and declines thereafter" (Fig. 4 and paragraph bridging pp. 2350-2351). It is no coincidence that the experiments described in the declaration measured gene expression after 24 hours. Boyce et al. conclude, "Much more work will be necessary to evaluate the...efficacy of AcMNPV as a tool for human gene therapy" (p. 2352, col. 2). Since this was published 18 months after the effective filing date of the instant application, any argument that the specification was enabling at the time the invention was made is not persuasive.

Claim 1 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory

Art Unit: 1819

action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be reached on Monday-Thursday from 8:00 to 4:30 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine Chambers, can be reached on 703-308-2035. The FAX phone numbers for group 1800 are 703-305-4242 and 703-305-3014.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Bruce Campell



**BRUCE R. CAMPELL
PRIMARY EXAMINER
GROUP 1800**